REMARKS

Claims 23-46 remain in this application. Claims 43-45 have been withdrawn.

Claim Rejections - 35 USC §103

At page 2, the Office Action rejects claims 23-42 and 46 under 35 USC §103(a) as obvious over SUMMERS (U.S. 6,733,797), in view of LOEW (Wiener medizinische Wochenschrift (1946), (2002) Vol. 152, No. 15-16, pp. 418-22, Ref: 40), and further in view of CARINI et al. (Planta Med 67 (2001) 326-330). Applicants respectfully traverse this rejection.

Independent claims 23, 35 and 36 are directed to methods for the enhancement of cognitive function and alleviation of mental fatigue comprising administering to a subject *Ginkgo* complexed with phosphatidylserine. As described in the specification, Applicants found unexpectedly that a *Ginkgo biloba* extract complexed with phosphatidylserine can be used to enhance cognitive function and alleviate mental fatigue significantly above the levels provided by non-complexed extract (*see*, page 3, lines 16-20 of the International PCT application). Thus, the claims relate to a pharmaceutical or dietary composition comprising a *Ginkgo biloba* extract complexed with phosphatidylserine.

The Office Action acknowledges that the combination of SUMMERS and LOEW fails to teach or suggest Ginkgo-

phosphatidylserine complexes, and fails to teach or suggest a method of using such complexes for the enhancement of cognitive function and the alleviation of mental fatigue as presently claimed (*see*, page 7 of the Office Action). The Office Action now relies on CARINI for teaching that Gingko-phosphatidylcholine improves cardioprotective activity and increases plasma antioxidant capacity, but then appears to extend this limited teaching to phosphatidylserine complexes and for also improving neuron function.

CARINI compares in rat the cardio-protective efficacy and the total plasma antioxidant activity of a standardized Gingko extract complexed with phophatidylcholine. CARINI is limited to studies in rats demonstrating complexation of Gingko with phosphtidylcholine, and to studies showing that after a short treatment a greater resistance of the heart to ischemia/reperfusion damage due to increased plasma antioxidant activity.

CARINI fails to teach or suggest the complexation of Gingko with other specific phospholipids other than phosphatidylcholine. Furthermore, CARINI fails to teach or suggest that Gingko complexed with phosphatidylcholine can be used in a possible method for the enhancement of cognitive function and alleviation of mental fatigue.

CARINI merely mentions, in the Introduction, the possible use of Gingko biloba for treating cerebral ischemia.

Even in this limited suggested use of Gingko, CARINI fails to demonstrate any experimental data in this regard. Indeed, CARINI fails to teach or suggest anything that the plasma antioxidant activity of Gingko-phosphatidylcholine complex may be somewhat useful in the brain, or in particular, the enhancement of cognitive function and alleviation of mental fatigue.

CARINI also fails to teach or suggest to one of ordinary skill in the art any reason to select another phospholipid among the many existing possibilities, and in particular, phosphatidylserine instead of phosphatidylcholine, and then to complex the phospholipid with gingko biloba extract.

CARINI, like SUMMERS and LOEW, fails to teach or suggest a Ginkgo-phosphatidylserine complex such as that described in the instant specification, and as featured in the instant claims. Specifically, the references fail to recognize that a *Ginkgo biloba* extract complexed with phosphatidylserine has significant effects above a non-complexed Ginkgo extract.

The presently claimed method enhances cognitive function and alleviates mental fatigue, i.e., it improves the factors related therewith such as the speed of memory and memory quality, increases accuracy and attention in activities in normal and healthy subjects, prevents deterioration of the speed and quality of memory in people with decreased cognitive functions, counteracts cognitive fatigue, and influences the mood (*see*, page 4, lines 6-13 of the present application).

As indicated at page 6, lines 22-28, and at page 7, lines 1-4 of the present application, "Gingko shows a strong affinity for phospholipids, resulting in the generation of bonds which markedly modify the physiochemical and spectroscopic characteristics of the new molecules . . . Therefore, the formation of Gingko phospholipids complexes enables the preparation of new biologically active compositions. In fact, they possess physico-chemical and spectroscopic characteristics which are markedly different from those of the original components and as such they can be incorporated as active principle into pharmaceutical formulations."

Because the complexation between Gingko and phospholipids modifies the physiochemical and spectroscopic characteristics with respect to the starting (parent) compounds, the different relevant therapeutic activity associated with the different corresponding derived complexes obtainable by complexation of Gingko with the many available different phospholipids was not foreseeable.

One of ordinary skill in the art, in view of the teachings of SUMMER, LOEW and CARINI, would have no reason to select phosphatidylserine, and then to select the 10 to 50% of phosphatidylserine as recited in claim 1, in order to achieve the desired therapeutic purpose - the enhancement of cognitive function and alleviation of mental fatigue.

As described in the specification, applicants have unexpectedly found that a Gingko biloba extract complexed with phosphatidylserine can be used to enhance cognitive function and alleviate mental fatigue significantly above the levels provided not only by the non-complexed extract but also by the extract complexed with phosphotidylcholine.

For all of the above reasons, the combination of SUMMERS, LOEW and CARINI fails to teach or suggest, and would not have rendered obvious the methods of claim 23, claim 35, and claim 36, and all of claims 24-34, 37-42, and 46 depending thereon. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

CONCLUSION

Entry of the above amendments is earnestly solicited. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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